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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,219

10/24/2005

Junta Yamamichi

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8285

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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,219

Applicant(s)

YAMAMICHI, JUNTA

Examiner

Dwayne K. Handy

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/05&12/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the step of "switching and passing the fluid". It is unclear to the Examiner what action is required to meet these method steps.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (6,649,358). Wada teaches a microfluidic device for performing high

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through put screening assays. The device is comprised of a substrate having a channels for flowing fluids and trapping substances in the channels. In column 17, lines 7-65, Parce teaches the flowing of an adhesion factor into a channel such that the adhesion factor binds to a substantial portion of a longitudinal segment (or segments) of the channel. A cell suspension is then flowed through the channel where cells are bound by the adhesion factor in the channel. The cells are then released by flowing a test compound stream along with a buffer stream through the channel to release and detect the cells. Parce also discloses similar sequences in column 19, lines 17-60; column 20, lines 20-50; and column 37, lines 13-43. See also Figures 4 and 6. Parce teaches the use of biological substances such as proteins and antibodies as the adhesion factors in column 18, lines 1-32. Parce discloses a wide variety of detection elements for detecting the labeled compounds in column 32, line 50 – column 34, line 43. The Examiner has considers the flowing of multiple streams through the channel concurrently as meeting the limitation of forming layers of fluid in the channel.

5. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (6,267,858). Parce teaches a microfluidic device for performing high through put assays. The device includes a plurality of channels (312-324) having particle retention zones (344) with biochemical system components (348) are held for mixing with test compounds that are on beads (346). See column 25. The individual beads are allowed to flow in the channels until the reach the particle retention zones where they then interact with the biochemical system components. A soluble signal formed from the

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interaction of the biochemical compound and the test sample is then detected by a detection system. See column 27, lines 1-50 and Figures 4A-4F. Parce teaches a wide variety of labels including antibodies and enzymatic proteins such as horse radish peroxidase in column 12, lines 27-65. Parce teaches detection elements in column 14, lines 52-67.

6. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhr (WO 01/07653). Kuhr teaches a flow through microchannel biosensor. The device is best shown in Figure 1. It is comprised of a capillary having multiple binding sites for binding different analytes of interest and an electrochemical cell detection element. Kuhr discloses binding compounds on pages 18-23.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wada (6,506,609) also teaches the focusing of fluids flowing in a microchannel into layers.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
September 28, 2007


Jill Warden
Supervisory Patent Examiner
Technology Center 1700